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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Hoffman & Baron) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER PADGETT, MARIANNE L	
			ART UNIT 1792	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,431

Applicant(s)

SHORT ET AL.

Examiner

MARIANNE L. PADGETT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/27/2004, 7/27/05, 4/18/08 & 6/17/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 6/17/8, 9/27/4.

1. **Claims 1-40** are rejected under 35 U.S.C. **112**, **second** paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1**, while depositing a monomer which is described as "at least one plasma monomer...", and where "means are provided which move the monomer source across a surface **to be treated** to manufacture a non-uniform plasma polymer surface" (emphasis added), no plasma treatment, or in fact any treatment is ever positively or necessarily performed, thus there is no positive claim of ever actually manufacturing any polymer surface, uniform or nonuniform, via plasma or otherwise, since no action is positively undertaken to transform any monomer into a polymer. Note use of "plasma" as an adjective does not provide any specific or necessary meaning, as it can imply an intent not yet accomplished, or a past action, as concurrent action, or even at none of the above.

Use of **relative terms** that **lack** clear metes and bounds in the claims, or **lack** a clear definition in the specification or in relevant cited prior art (i.e. commensurate in scope with claim language), is vague and indefinite. Relative terms include "non-uniform", "volatile" (claims 7-11 & 13, noting virtually any material is "volatile" dependent on conditions that cause evaporation or sublimation), "high" (claim 33), "low" (claim 33), & prefix "micro-" used in "microfluidic", "microarray" & "microtitre", or the prefix "macro-" in "macromolecules" (claim 37). Note that supplying prior art references that provide definitions of high-density polyethylene or low-density polyethylene &/or macromolecules is an acceptable means of supplying definition for such terms, as are clear statements on the record that clearly indicate that specific terms, such as macromolecules or microarrays, are not intended to indicate particular size ranges, in order to clarify scope in the claims.

In the independent **claim 1**, see "non-uniform" describing "a non-uniform plasma polymer surface", which is a relative term, as what may be considered nonuniform is not clearly defined, i.e. it is uncertain what about the plasma polymer surface is nonuniform, is it rough & what degree of roughness is

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considered nonuniform; is it patterned; is the deposition nonhomogeneous & what scale of nonhomogeneity would be sufficient to call it nonuniform; etc? Review of the specification found this terminology used on page 1, line 3; and page 6, lines 18 & 26, but no definition. While page 7, lines 29-30 provide an example of possible scope/intent with the concentration of the plasma polymer being nonuniform across the surface, an example is not a definition, thus does not define the scope of a relative term in the claims. It is noted that the term "non-uniform" is also used in claim 31 to describe the chemical composition of a line, track or dot, but this claim provides a context for the nonuniformity being "along its length and in height" with respect to the line, track or dot", thus may be considered sufficiently defined in claim 31.

Similarly, the scope of "assay product" (introduced in **claim 34**) is unclear, as no definition was found in the specification as to what "assay product" encompasses, thus its scope is uncertain. The term was found used without definition on page 1, line 10; page 2, line 27; page 11, lines 12-16; & page 13, lines 16-20, where two examples are given of "a microarray" and a "microtitre plate", but again examples are not definitions and themselves contain "micro-" which is a relative size prefix, thus are also relative terms. It further noted that while claim 36 is dependent on 35, which is dependent on 34, requires the "assay product" to be both a microtitre plate & a microarray, the relationship of these two requirements is not defined, so the structure of the product claim is not clear. Furthermore, while the assay product comprises a "substrate comprising a surface **obtainable** by the method... in claim 1" (emphasis added), independent claim 1 has little clearly definable structure for reasons as discussed above, merely produces a substrate of undefined material, which has at least one monomer deposited in a manner which if it is treated might somehow be "non-uniform", but it is not clear how or in what way, if this substrate of unknown structure has any direct connection or relationship to either the microarray or the microtitre plate, except that it is also at least some unspecified part of the "assay product". For purposes of examination, lacking a clear definition, it is considered that "an assay product" may be considered to

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encompass an unspecified object that is used in an unspecified test for an unspecified purpose, except that it is a test of something, i.e. something is being assayed. However, the assaying, i.e. testing, is an intended use & does not provide necessary structural limitations *per se*, especially since no particular test is defined. Note that **claims 39 & 40**, which also express intended use of "for use with an array printer" or "... an array reader", also provide no positive structural requirements as written. Therefore for examination purposes, as written the claimed "assay product" of **claims 34 & 39-40**, does not appear to have anything distinguishing it from the substrate of **claim 32**, while **claims 35-36** require the presence of "a microarray", the claimed microarray need not be formed of or part of the substrate having a surface structure that might have been produced by the process of claim 1, it need only be used in a structure that also contains a substrate with a monomer, plural monomers or maybe a polymer on a surface which is by definition composed of monomers, however as noted above the polymer has not been positively formed.

In **claim 4**, line 2, "the surface" is vague and indefinite, since there are at least two different surfaces introduced in **independent claim 1**, i.e. "at least one surface of a substrate" in line 1, which might be the same as "a surface to be treated" that is introduced bridging lines 3-4, and "a non-uniform plasma polymer surface" that is the surface after treating & appears to be intended to be the least one surface of the substrate on which one plasma monomer was deposited, except as written there is no necessity that the plasma monomer came from "the monomer source" (lacks proper antecedent basis), nor is "one plasma monomer" the same thing as "plasma polymer" (i.e. a single molecule which has the potential of being formed into a polymer, but is not a polymer & it is unclear how plasma modifies monomer, as this is nonstandard terminology), thus as claimed there is no clear relationship between the deposited "plasma monomer" & the manufactured "non-uniform plasma polymer surface". Also see **claims 6 & 28** for further unclear references to "surface".

In **claim 5**, it is unclear how "a surface" relates to the multiplicity of surfaces present in independent claim 1 & how the "two or more plasma polymers" & the "at least two monomers" relate to

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the plasma polymer & plasma monomer of the independent claim. **Claim 6**, dependent on claim 5, further lacks clear association with previously introduced similar terminology. Note while claim 6 has the potential for defining what about the plasma polymer surface is non-uniform, as presently written, the relationship is not clear.

In **claims 12 & 18**, the scope of "an ethyleneoxide-type molecule" is unclear, as it is uncertain what constitutes a "type", i.e. is any molecule that contains an ethylene oxide unit in any position a claimed "type", or must ethylene oxide be the backbone of the molecule, or is any molecule of either of these "types" & derivatives thereof included, or what? For purposes of examination, any molecule that might be construed to be a claimed "type" will be considered to be included.

Claim 15, hence **claims 16-23** dependent thereon, appear to be self-contradictory as written, since a polymer by definition consists of more than "a single monomer", as it is required by definition to be formed from plural monomer units. Given the context this appears to be a phrasing problem (similar to the use of "...one plasma monomer" in the independent claim), where the probable intent is that the polymer is formed from monomers that are all the same chemical molecule or unit, so the phrasing could also be considered ambiguous.

It is unclear to the examiner how **claims 16 & 17** differ, given that the requirement is already for "a single monomer" due to the dependence on claim 15, so if "said monomer consists essentially of in an ethylenically unsaturated organic compound", claim 15 has already defined it to be a "single", with it further noted that neither of the "consists essentially of" appear to make any difference, since the requirement of "a single monomer" (given above probable intent), already excludes the presence of other chemical compounds being the monomer. For these reasons, the intended scopes of these claims are unclear. Alternatively, **Claim 17** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

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cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 20, hence its dependent **claim 21**, contradicts the requirement of claim 15, since a monomer is a compound, thus cannot consist of "a mixture of two or more ethylenically unsaturated organic compounds" and still be "a single monomer" in either the literal sense of claim 15, or it's probably intended meaning, as discussed above. While a monomer might be synthesized from a mixture of compounds, once that synthesis has occurred, there are no longer separate compounds in the monomer, thus no longer a mixture of compounds. If one has a mixture of different compounds, one cannot have a single monomer, but would have a mixture of monomers.

With respect to **claims 22 & 23**, analogous to above discussion, it is unclear what "consists essentially of" adds that is not already required by "single" in claim 15 from which these claims depend.

In **claim 24**, it is uncertain if the claimed "vapour pressure" is intended to describe a property of the monomer selected for use, or is requiring that when performing the process, presumably during deposition of the monomer, it has a partial pressure of at least 6.6×10^{-2} mbar, thus this claim limitation is ambiguous as written. Note if the former meaning is intended, the pressure value is lacking in significant meaning, as other environmental conditions must be specified, such as temperature, etc. in order to define at materials' partial pressure, but if the latter is intended it is noted that none of the examples employ a reaction pressure within the claimed range, as all the examples use pressures lower than the minimum value of 'vapor pressure' claimed.

In **claim 26**, "... one organic monomer with at least one hydrocarbon" is ambiguous, as it is unclear whether the hydrocarbon is required to be part of the organic monomer, or if the organic monomer is one component of the copolymer, with the hydrocarbon being the other monomeric component that makes up the copolymer. Claim 27, dependent from claim 26, does not clarify this issue.

In **claim 30**, "the dots and/or lines" is confusing or ambiguous, with respect to the dependence on claim 28, given that claim 28 only deposits the monomer "in spatially separated dots", thus the option of "lines" has no clear relationship to claimed process limitations, such that claim 30 may be considered to contradict claim 28 as the dots therein are optional, not required. Furthermore, in claim 30 the requirement that these dots &/or lines "are of different polymer chemistry" is unclear, since with respect to what they are of different polymer chemistry is uncertain.

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As noted above, claim 30 appears to have limitation options contradictory to claim 28 from which it depends.

Claim 31, depended on claim 30, extenuating the problems therein, as it adds another possible previously unclaimed option of "track", when claiming "the chemical composition of the line, track or dot is non-uniform along its length and in height". Also note that "the chemical composition" lacks proper antecedent basis, hence if its intent was to further modify, or for the claims as written, actually define what was meant by "different polymer chemistry", it has failed to do so.

In **claim 33**, the Markush group is improper, since the species list therein are not mutually exclusive. Specifically, besides having a listing of exemplary plastics in parentheses, nylon & nitrocellulose are also plastics, & metal films are a subset of metal, while glass & quartz are subsets of ceramics.

In **claim 37**, it is unclear what structure the product that comprises the substrate of claim 32, is intended to encompass, as "for separating cells and/or proteins and/or macromolecules" provides no necessary structure, only intended use, thus as claimed this product appears to have no structure not

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already required by claim 32, which only has structure as is positively produced in claim 1, whether or not it is produced by the same process, i.e. a monomer on a substrate.

2. The **disclosure is objected** to because of the following informalities: proofreading is needed, for example, on page 2, line 10, there are inappropriate spaces between parts of what is probably intended to be a single US patent number; or such as found on page 9, lines 7, 8, 16, 21 & 30, numerous uses of "eg" that are probably intended to be --e.g. --; or on page 21, line 28, the second pressure value lacks proper superscripting. This should not be considered a complete listing of issues for correction.

Appropriate correction is required.

3. **Claims 24 & 28-29** are **objected** to because of the following informalities: "monomer (s)" is objected to for using improper spacing, i.e. if the intent is to show optionally single monomer or plural monomers, there should be no spacing between monomer & (s). Also note that in claim 29, "is are" lacks the "/" which makes the verb options alternative in claim 28.

In claim 24, as this is a US patent, the American English spelling for "vapour", i.e. -- vapor --, should be employed.

Appropriate correction is required.

4. The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-10, 14-17, 19-22 & 24-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting** as being unpatentable over claims 29-47 & 50-53 of copending **Application No. 11/269,427**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to overlapping subject matter, where the immunoassay product is considered a subset of the claimed assay product, where both may be made using plasma polymerized deposits of like or overlapping materials, such that the overlapping scopes are obvious variations of each other with respect to the presently claimed microarray that might also be a microtitre plate, this is considered to be overlapping with, if not identical to, the claimed multiwell assay plate, with the claimed multiwell assay plates suggesting that the structure of the surface, as it relates to the deposited polymer, thus monomers, is nonuniform. The present method claims differ from related method claims of the copending case, in that the present claims require means for movement of the

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monomer source with respect to the surface being treated, which action is not mentioned in the copending method claims, however there are a multitude of obvious reasons for movement of a source material during deposition processes, such as deposition on a continuous substrate, such that the substrate is moved past the source of deposition material; or desired pattern deposition as suggested by microarray or multiwell uses & typical structures therefore, where selected deposition (e.g. different concentrations) might be desired on only wall structures or on only well bottom structures, or movement to enable distribution over large planar or three-dimensional surfaces, or the like. Therefore, claimed monomer source movement is considered an obvious variation on typical process procedures suggested by claim limitations & conventional processing procedures. It is noted that with respect to the product claims, whether or not there is relative movement of the monomer source in producing the product is irrelevant, as such movement produces no necessary structure, nor are various unnamed but possible structures that might be produced by such movement necessarily only produced by relative source movement.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **Claims 32, 34 & 37-40 are provisionally** rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1-27 of copending Application No. **10/599,943**. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the copending claims appear to be currently directed to use of substrates that may have been produced by the presently claimed process, they may be considered to read on the claimed substrate structure, noting they are used for dissociating biological entities, such as cells or macromolecules, from the substrate & employ monomers as claimed in their "plasma polymer".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. **Claims 1-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-43 of copending Application No. **10/560,210**. Although the conflicting claims are not identical, they are not patentably distinct from each other because while limitations are claimed in different orders, the various limitations of the present claims, are also claimed in this copending case, where present independent claim 1 encompasses the process of copending (210)'s independent claim 1, which is narrower in that it requires further coating on the plasma polymerized surface of a "binding entity", which is considered to read on a binding site. Note that copending claim 1's limitation of moving monomer &/or surface relative to one another covers the options of relative movement as expressed in present claims 2 & 3. Also note how that N-vinyl pyrrolidone in copending claim 15 is a heterocyclic unsaturated compound. While the copending claims do not have the "for use" limitations of present claims 39 & 40, they have the claimed substrate structure, & the "for use" limitations have no discernible or necessary structure, hence are not considered to provide any effective further limitation to these product claims, thus read on the claimed assay products & microarray & microtitre plates, etc., of the copending case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. **Claims 32-40 are rejected under 35 U.S.C. 102 (b)** as being clearly anticipated by **Goessl et al.** (Plasma Lithography -- thin-film patterning of polymers by RF plasma polymerization...", J. Biomater...).

Goessl et al. teach micropatterned cell culture plates that have a layer of plasma polymerized tetraethylene glycol dimethyl ether on a polyethylene terephthalate (PET) substrate, with a patterned layer of plasma polymerized tetrafluoroethylene thereover (abstract; "2.3. Substrate preparation" on p. 742-743), which micropatterned structures may be seen to have an array structure, as illustrated in fig. 3 on p. 746-748. It is noted that while the patterning of the second plasma polymerized layer is performed by

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first depositing a photomask, which is removed after the conformal deposit of the fluorocarbon polymer to thus produce a patterned layer, this is irrelevant to the product claims, as process limitations in product claims only further limits product claims with respect to structure they necessitate, where as noted above the process claims provide for very very little required structure. Goessl et al.'s use of photolithographic techniques employing a mask to produce the resultant pattern, provides a nonuniform structure as a result of the process, with different concentrations & thicknesses of fluorocarbon plasma polymer produced thereby on the surface, which structure is encompassed by what little structure is required in applicants' product claims.

9. **Claims 32-40** are rejected under 35 U.S.C. **102 (b)** as being clearly anticipated by **France et al.** (Plasma Copolymerization of Allyl Alcohol/1, 7-Octadiene...) or French et al. (Attachment of Human...).

In **France et al.** (Plasma Copoly...), particularly see the abstract; the introduction, especially 1st, 3rd & 6th paragraphs; experimental section, especially the plasma copolymerization discussion bridging cols. on p. 1177 concerning plasma co-polymerization of allyl alcohol & 1, 7-octadiene monomers within RF frequency plasma onto substrates, inclusive of aluminum foil, glass slides & tissue culture wells, at typical pressures of 4.0×10^{-2} mb & cell attachment assay discussion in the 1st col. of p. 1178 that discloses six well tissue culture plates, where the wells were coated with the plasma copolymer, which disclosure is considered to read on nonuniform, binding sites, microarray & microtitre plate configurations, & consistent with claimed intended uses.

In **French et al.** (Attachment of Human...), see teachings in abstract & experimental section equivalent to those discussed above with respect to the other French et al. reference, for purposes of rejection of the present product claims.

10. **Claims 1-2, 5, 10, 13-14, 24, 29 & 32-33** are rejected under 35 U.S.C. **102 (b)** as being clearly anticipated by **Renner et al.** ((DD 94657), see translation).

Claims 3, 26 & 33 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Renner et al.**

Renner et al. teach a plasma polymerization technique, where the substrate, a magnetic storage medium exemplified by disks or tape, is kept in motion during the plasma polymer coating process, and where the composition & degree of polymerization of the deposited polymer coating is changed by control of the deposition process parameters &/or mixing ratio of various monomers, or a monomer & inert gas, so that the coating has different properties at different distances from the substrate surface. In example 1, plasma deposition on magnetic recording media disc substrates is performed at a constant pressure of 5 Torr, with an initial partial pressure of hexamethyldisiloxane of 10^{-3} Torr, that is continuously increased during deposition in order to reduce the degree of polymerization, thus producing a nonuniform deposit. In example 2, a magnetic storage medium in tape form (e.g. substrate would be polymeric = plastic) is passed between electrodes in a plasma atmosphere of octamethyltrisiloxane at 0.5 Torr (i.e. >0.05 Torr = 6.6×10^{-2} mb), using two electrode systems of different lengths with plasma being generated at different voltages to effect the taught differentiated plasma polymer deposition. In the translation, besides the examples, also see the 2nd-5th paragraphs on the 2nd page & claims, esp. 1-3.

While the specific examples only employed a single type of monomer compound, i.e. hexamethyldisiloxane or octamethyltrisiloxane, both organosiloxane compounds having saturated hydrocarbon ligands (i.e. may be considered a saturated organic compound & a type of hydrocarbon compound), the generic teachings also indicate that mixtures of various monomers may be employed, thus reading on copolymeric depositions. These teachings are considered suggestive of copolymeric depositions involving at least one organic monomer with at least one hydrocarbon, as suggested use of monomer mixtures would reasonably have been considered with respect to the to exemplified monomers employed with other monomers or each other, such that it would've been obvious to one of ordinary skill

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in the art via routine experimentation to determine reasonable & effective monomer mixtures given these considerations.

Also note that depositing on tapes, may be considered effectively depositing in tracks or lines.

Note with respect to substrate composition, while magnetic tape medium, as far as the examiner knows are always polymeric, i.e. plastic, the translation does not actually say that the tapes coated are plastic, however it would've alternatively have been obvious to one of ordinary skill in the art to employ conventional compositions for magnetic tapes, i.e. plastics, as that is what is standardly known to be employed.

While discussion in the translation indicates movement of the substrate with respect to the plasma, which may be considered the monomer source, with indication that the storage medium, i.e. substrate is kept in motion during the plasma polymerization process, it would have alternatively have been obvious to one of ordinary skill in the art that equivalent relative effects would have been produced by moving the plasma source with respect to the substrate, such that this would have been an obvious alternative, dependent on particular shape of the magnetic recording medium desired to be protectively coated. In

11. **Claims 32-34 & 37-40** are rejected under 35 U.S.C. **102 (b)** as being clearly anticipated by **Timmons et al.** (6,306,506 B1).

Timmons et al. teach a plasma polymerization process that enables retention of functional groups (e.g. amine groups, carboxylic acid groups, etc.) on the surface that may act as binding sites, where they provide examples of plasma polymerization of various monomers, so as to produce a gradient layer on substrates inclusive of PET, where these plasma polymer coated surfaces can be treated with a solution containing a molecule, such as amino acid hexafluoro-DL-valine that is considered to read on a macromolecule, which is deposited thereon, thus separated from the solution & which thereafter may be

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subject to analysis (i.e. such a product may be considered an assay product). See the abstract & examples such, as example 1 bridging cols. 14-15.

12. **Claims 1-4, 8, 10, 12, 14-19, 22, 24 & 32-33** are rejected under 35 U.S.C. **103(a)** as being unpatentable **Badyal et al.** (6,358,569 B1), in view of **Renner et al.** (discussed above in section 10), and optionally considering **Nomura** (6,022,602).

Claims 5-6, 9-11, 13, 20-21, 23, 25-27 are rejected under 35 U.S.C. **103(a)** as being unpatentable **Badyal et al.** (6,358,569 B1), in view of **Renner et al.**, as applied in claims 1-4, 8, 10, 12, 14-19, 22, 24 & 32-33, and further in view of **Nomura** (6,022,602).

Badyal et al. teach pulsed plasma polymerization of monomers, such as unsaturated-carboxylic acid, or acrylic acid or ethylene oxide or styrene oxide, to deposit on substrates that may be porous or microporous material, such as polyethylene or cellulose, etc., where the coating may be applied such that it is continuous & impervious, or the process may be stopped at an earlier stage such that the apertures in the porous material are not completely filled, dependent on desirability for particular enduse, which is inclusive of uses requiring biocompatible properties. Note that the option of incompletely filling pores on porous material created a plasma polymerize surface that may be considered nonuniform across the surface. An exemplary procedure discusses plasma polymerization of acrylic acid monomer input into the plasma reactor as a monomer vapor admitted via a needle valve to a pressure of 0.2 mb. Particularly see the abstract; col. 1, lines 1-col. 2, lines 5 & 40-58, esp. col. 1, lines 43-54 & 62-col. 2, line 5; col. 3, lines 38-45 & 54-col. 4, lines 12; col. 5, lines 37-41.

Badyal et al. differs from the claims by not discussing if there is any movement of substrate or monomer source during the plasma polymerization process, however **Renner et al.** (discussed section 10), who also discuss plasma polymerization processes, notes the importance of motion between substrate & plasma during the precipitation and polymerization process in order to enhance homogeneity of the polymer at is being deposited, such that it would've been obvious to one of ordinary skill in the art to

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similarly employed motion in order to insure homogeneous distribution of the polymer, which affect is considered to be complementary to the above-mentioned ability to deposit such that pores are not completely filled dependent on timing of the process, as it is consider that these two effects would not hinder each other & homogeneous deposit on all raised, i.e. non-pore areas, would have been beneficial for producing desired functionalized composition, thus properties, thereon.

It is further noted that the type of motion employed, would have been expected to be depended on the particular type of porous substrate being treated, with **Nomura** ((602): abstract ; figures, esp. 1; col. 1, lines 15-60; col. 2, lines 32-65; col. 3, lines 38-65; col. 4, lines 35-50; col. 7, lines 15-50; col. 8, lines 65- col. 9, lines 40 & 56-63; col. 10, lines 5-10 & 50-59; col. 12, lines 7-20 & 42-67; col. 13, lines 7-25 for monomers & 26-44+ for more parameters; & examples) being optionally considered in this respect, due to discussion of plasma polymerization on the interiors of continuous tubing, such as may be used for medical devices like catheters, vascular grafts, etc., where the tubing is passed through a plasma polymerization zone, thus is consistent with the type of movement taught in the secondary reference of Renner et al. for continuous tape substrates, thus further providing for the obviousness of such movement. It is also taught that such tubing, which is porous, but has low porosity, may require their techniques of having periodic sequential openings to allow input of monomer gases to the interior, or their background discussion that it was known to perform such plasma polymerization on sufficiently porous tubing. Nomura (602)'s technique provides for movement of the substrate pass the monomer source, so as to provide input of monomer gas into the tubing interior, where it is desired to be plasma polymerized, thus indicates means of effectively producing plasma polymerization processes as discussed in Badyal et al. for interiors of tubing, plus providing motivation to do so on tubular substrates. With respect to particular deposition materials, Nomura (602) provides teachings of using monomer vapors or mixtures of monomer vapors, with further discussion of monomers that may effectively be deposited via plasma polymerization processes on such surfaces, inclusive of tetrafluoroethylene to create polyfluorocarbon surfaces, &

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siloxanes such as hexamethyldisiloxane to create polysiloxane deposits, alkanes & alkenes, acrylic acid, allylamine, benzene, styrene, diaminocyclohexane, etc., such that it would've been further obvious to one of ordinary skill to deposit such monomers on porous surfaces via plasma polymerization as discussed in Badyal et al., in view of Renner et al. as discussed above, given their effectiveness in analogous processing has been demonstrated, as has their desirability for enduse is on analogous types of substrate material, especially with respect to deposition of fluorocarbon as Badyal et al. teaches the desirability of sequentially fluorinating the surface, thus Nomura provides an option or means for doing so with less steps.

13. **Claims 1-27, 29-33 & 37-38** are rejected under 35 U.S.C. **103(a)** as being unpatentable **Muguruma et al.** (7,087,149 B1 \equiv WO 00/63685), in view of **Renner et al.** (see section 10 above).

Claims 34-36 & 39-40 are rejected under 35 U.S.C. **103(a)** as being unpatentable **Muguruma et al.** (7,087,149 B1 or WO 00/63685), in view of **Renner et al.**, as applied in claims 1-27, 29-33 & 37-38, further in view of **France et al.** ("Attachment..." or "Plasma...") or **Goesl et al.**, all discussed above. I

Muguruma et al. teach making a biosensor structure, where a preferred embodiment has 2 plasma polymerize layers, with an intervening patterned electrode layer, such that the resultant structure may be considered to be nonuniform, in that the surface plasma polymer is not plannar & does not have the same thickness over the whole surface, but the thickness changes where it crosses the electrode pattern having lines of thicker polymer at the edges of the electrode pattern. Also, where the first plasma polymer is directly overlaid by the second deposited plasma polymer, there are at least two plasma polymers formed on the surface, such at the composition where they interface may be considered different, providing a compositional nonuniformity. The surface plasma polymer provides binding sites for biomolecules, such as enzymes, where the overall structure is used for analysis purposes. With respect to plasma polymer deposition processes, Muguruma et al. teach that the plasma polymers may contain one or more

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functional groups inclusive of acids (-COOH), hydroxy (-OH), amines, -CH=CH_2 , ethylene oxide groups, etc., where such functional groups may be supplied in single monomer gases or mixtures of monomers, & include such compounds as allylamine, methanol, acetic acid, acrylic acid, hexamethyldisiloxane, hexamethylcyclotrisilazane, etc. Substrate boards may include glass or plastic or silicon or cellulose. Muguruma teach that plasma polymerization conditions can be appropriately set by one of ordinary skill in the art dependent on monomer gas employed, where exemplary pressures for gases such as hexamethyldisiloxane or acetonitrile monomers include pressures of 1-10 Pa, i.e. 0.1-0.01 mbar. In Muguruma et al., particularly see in the US patent (considered to provide the translation for the Japanese PCT document), the abstract; figures 1-2; col. 1, lines 10-25+; col. 3, lines 15-32 & 66-col. 4, lines 20 & 38-col. 5, lines 30+; col. 6, lines 31-67; col. 7, lines 7-22; col. 8, lines 6-50; & examples, such as example 1 on cols. 11-12.

Muguruma et al. differ by not discussing whether or not movement occurs with respect to substrate & monomer source, however Renner et al. as discussed above in sections 10 & 12, in provides reasons why such relative movement during plasma polymerization is desirable, thus it would've been obvious to one of ordinary skill in the art to employ such movements in order to optimize their plasma polymer deposition & create more effective biosensors due to effective distribution of functional groups on the surface.

Muguruma et al., in view of Renner et al., do not discuss array or microtitre structures, however biosensor is are commonly employed in such structures as discussed by France et al. ("Attachment..." or "Plasma...") or Goessl et al., hence it would've further been obvious to one of ordinary skill in the art, to employ the particular individual structures as taught by Muguruma et al., in such array structures, as the ternary references provide use & desirability for such structures thus motivating claimed products made by the techniques of Muguruma et al.

14. **Claims 1-2, 4-11, 14-17, 19-27, 32-34 & 37-40** are rejected under 35 U.S.C. **102(b)** as being clearly anticipated by **Nomura et al.** (5,843,789).

Nomura et al. ((789) abstract; figures 1-2; col. 3, lines 27-57; col. 4, lines 10-20; col. 5, lines 10-60; col. 6, lines 5-50; col. 7, lines 7-34 & 50-col. 8, lines 25 & 55-65; col. 9, lines 1-10, 22-40 & 55-65; col. 10, lines 12-50; and examples & claims) teach plasma polymerization deposition of claimed monomers on porous substrates that may be rotated on a disk so as to pass through a plasma formed with those monomers, where the coating deposited on the porous substrate does not clog or fill the pores, thus is considered to be nonuniform across the surface. This improved porous material is taught to be used for blotting analysis of proteinaceous & genomic matter, or in immunoassay analysis.

15. **Claims 32-34 & 38** are rejected under 35 U.S.C. **102(b)** as being clearly anticipated by **Oka et al.** (4,562,725).

Oka et al. teach a moisture sensor having a quartz disk substrate with the pair of gold electrodes thereon, where a plasma polymerized thin film is deposited on a limited central region of the electrode, such that the plasma polymer is nonuniform across the surface. **Oka et al.** teach forming the plasma polymer from monomers, such as vinyl aromatic polymers (e.g. polystyrene, styrene-divinyl benzene copolymers, styrene-final alcohol copolymers, etc.), in RF plasma apparatus, where the electrodes on the substrate may be employed in the deposition process & masking is used to limit the deposition, however as previously discussed, only the structure is relevant in the product claims, not the method of creating the nonuniformity. Note that a moisture sensor is a type of measuring device, thus is encompassed by the broad claim of "an assay product", & as it is concerning measuring moisture, a fluid, via binding sites on the surface, it may also be considered to read on the claimed "microfluidic device or part thereof".

16. **Claims 1-2, 4-6, 9-11, 13-17, 19-23, 25-27, 32-33 & 37-40** are rejected under 35 U.S.C. **102(b)** as being clearly anticipated by **Hu et al.** (5,463,010).

In **Hu et al.** (010), see the abstract; figures, especially 1-2; col. 1, lines 7-15+; col. 3, lines 48-col. 4, lines 18, 33-37, 42-67+; col. 6, lines 13-col. 7, lines 35; col. 8, lines 5-40 & 46-col. 11, line 3; & examples e.g. Ex.2 & 3 on cols. 11-12, which teach plasma polymerization using only a single type of monomer of aliphatic hydrocyclosiloxane, or mixtures of these siloxane monomers with comonomer(s) inclusive of fluorocarbons or organo based monomers or functional terminated monomers (e.g. ethylene, allylamine, trimethyl silyl allylamine, hydrocarbons, unsaturated amines...), to affect polymer or copolymer depositions via RF plasma onto substrates inclusive of silicon catheters, metal wire and fibers, such as polypropylene microporous hollow fibers, to produce "membranes" thereon. Taught enduses include biocompatible surfaces in biomedical devices. Note "aliphatic" includes both saturated & unsaturated hydrocarbons, i.e. alkanes & alkene, and the hydrocyclicsiloxanes are heterocyclic compounds. Since the deposit the coating is described as a "membranes", it is considered an indication that the plasma polymer coated substrate remains microporous, thus may be considered nonuniformly coded across the surface with respect to the microporous structure, i.e. the pores aren't plugged.

17. **Other art of interest** includes: Kurosawa et al. ("Absorption of Anti-Human IgG to Plasma Polymerized Allylamine Film Formed on Silver Plate") directed to further plasma polymerized depositions used for assay purposes; Timmons et al. (5,876,753 & 2003/0113477 A1 & 2002/0004104 A1) which contain teachings analogous to those found in Timmons (506) discussed above.

Kolluri et al. (6,277,449 B1) provide teachings substantially similar to that of Muguruma et al. or Badyal et al., for producing plasma polymerize coatings with binding sites for further depositions, where the nonuniformity in the deposits of Kolluri et al. may be considered to be on the molecular level, such as illustrated in various functionalize surfaces, for example the resulting surface in figure 37 has three different functional groups thereon, thus may be considered to be nonuniform across the plasma polymerized surface in this respect, however such a rejection is redundant at this time.

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18. **Any inquiry** concerning this communication or earlier communications from the examiner should be directed to **Marianne L. Padgett** whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Marianne L. Padgett/
Primary Examiner, Art Unit 1792

MLP/dictation software

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